

**K990916 INDIRECT FLUORESCENCE ASSAY FOR ANTI-NATIVE
DNA IGG ANTIBODY**Apr 21, 1999
34 days to decisionK990916 · Product code: **KTL** · Immunology
Source: <https://www.510kdatabase.net/k990916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Indirect Immunofluorescent Solid Phase (KTL)
Date received	Mar 18, 1999
Decision date	Apr 21, 1999
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stellar Bio Systems, Inc.
Location	Columbia, MD, US
Contact	JOHN BREWER
510(k) history	7 submissions · 7 cleared · 1988-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990916/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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